REMARKS/ARGUMENTS

Favorable reconsideration of this application, in view of the present amendments and in light of the following discussions, is respectfully requested.

The undersigned would first like to thank Examiner Brown for granting an interview in this application. While arguments concerning why Perkins was not believed to be applicable, based on the anatomy of human beings, what Perkins' discloses and how the present invention works, no agreement was reached on some claims. Thus, this refilling was made necessary.

Claims 1-13, 15-21, and 23-49 are currently pending in the application. Claims 14 and 22 were previously cancelled, and claims 1, 28, 32 and 34 have been amended herein. In addition, new claims 39-59 have been added by the present amendment. The changes to the claims, as well as the newly added claims, are supported by the originally filed specification, including the drawings, and are not believed to introduce any new matter.

The undersigned thanks the Examiner for allowing claims 5, 10-13, 27 and 32-33. Further, the Examiner indicated that claims 8, 9, 17, 18, 30, 31 and 36 would be allowable if rewritten in independent form. New claims 46-49 present, in independent form with minor edits, claims 8, 17, 30 and 36, respectively. Thus, new claims 46-49 are believed to be in allowable condition and notice thereof is respectfully requested.

Claim 1 has been amended to correct one ambiguity and to emphasize that the compression in the central area is greater than the compression value in the two locations directly adjacent the central area. This is to permit the sacrum to be held more firmly and provide compression areas directly adjacent the central area so that the pelvis bones can relax or nest into the softer less compressive material, thereby controlling the spinal orientation of the seated user.

Claim 28 has had a § 112 issue corrected now includes end portions located outwardly from each of the two adjacent side portions, each of which is next to the central portion, and that the central portion has a harder compression level to emphasize that the two adjacent side areas act as release areas with less compressive force being applied to the seated user than is applied by the central portion.

Claim 32 has been amended to be more specific as to the adjacent side portions, to clearly locate the end portions, to emphasize that the central portion has a higher compression value than the compression value of each adjacent side portion, and to add a third compression area at the end portions with a compression value that is in between that of the central and the adjacent side portions, respectively.

Claim 34 has been amended to emphasize that the first compression value in the central portion is greater than the compression value in the second compression area, to more clearly position the end portions, and to clearly claim that the second compression area is located between respective sides of the central portion and each respective end portion.

In the outstanding Office Action, Claims 1-4, 6-7, 15-16, 19-21, 23-26, 28, 32, 34 and 37 were rejected under 35 U.S.C. § 102(b) as anticipated by Perkins. (U.S. Patent No.4,572,578). This rejection is traversed.

First, the Examiner is incorrect in stating that Perkins discloses a "portable sacral support." Perkins' invention concerns what he describes as a "Back Rest." In Col. 1, lines4-10, Perkins describes his invention as a back rest that will provide support of the thoracic, cervical and lumbo-sacral areas. Exhibit A, from "Clinical Biomechanics of the Spine" Second Edition by White and Panjabi, shows on page 104 that the spine is comprised of the upper cervical region, the middle or thoracic region and the lower lumbar region. The "lumbo-sacral" term generally refers to the L5-S1 area. The sacrum is below the lumbar and the coccyx is located below the sacrum, with the sacrum and coccyx being positioned between the pelvic bones. Consequently, Perkins is disclosing a back rest that will support the upper, middle and lower back and will not effect, support or contact the sacrum in any concentrated manner.

Interestingly, there is no refrence to the sacrum by itself or to the coccyx by itself, in Perkins. It is also notable that Perkins employs a convex curvature at the bottom of his back rest which actually curves away from a user back toward the seat. That is opposite to the concepts claimed herein where the claimed invention places pressure on the sacrum. In deed, the wedge shape of the present sacral support, with a greater width at the bottom and with the curve of the

upper portion, effectively extends further out at the bottom. Because of the bottom curvature used by Perkins, the Perkins back support would not be able to apply pressure onto the sacrum as it curves in the wrong direction. This is but one reason why Perkins does not support the sacrum. There are others as well.

The figures in Perkins show, and he describes, a vertically extending slot or groove 19 and 19a. The description is as follows:

> The two thoracic members 15 are spaced apart to provide a slot or groove 19 between them, the purpose of which is to receive and accommodate the bony prominences of the spine. (See, col. 1, lines 63-66)
>
> Referring now to FIGS. 3 and 4, as well as FIG. 2, lumbo-sacral support members of plastic foam material are provided at 25 which have the curvature of the power portion 13 of the frame 11 and they are spaced apart to provide a continuation 19a of the groove 19. (See, col. 2, lines 5-11)

This clearly shows that the back rest 10 includes a vertically extending groove 19/19a that runs from top to bottom. That groove 19/19a is significant in understanding why Perkins' backrest does not teach the present invention.

In the lumbar section of the Perkins back rest, two foam areas 25 are provided each of which lies adjacent groove 19a.[1] Out board from these two foam areas 25 are the "pillow-like support members 26" that Perkins describes as providing kidney support. Each kidney support 26 is placed on top of the underlying foam of the back support 10 and the continuation of areas 25. Consequently, two layers of foam are present in the area of the kidney supports, i.e., the underlying foam from which the back rest 10 is formed as well as the added kidney supports 26. Theses two layers of foam, at the outer portion of the back rest, are shown in Figs. 3-5. In fact Fig. 3 shows a front layer of the cloth, the first foam layer 15 and the kidney piece 26 (Note: there are different cross hatchings used on each of the three layers). It should also be bourn in

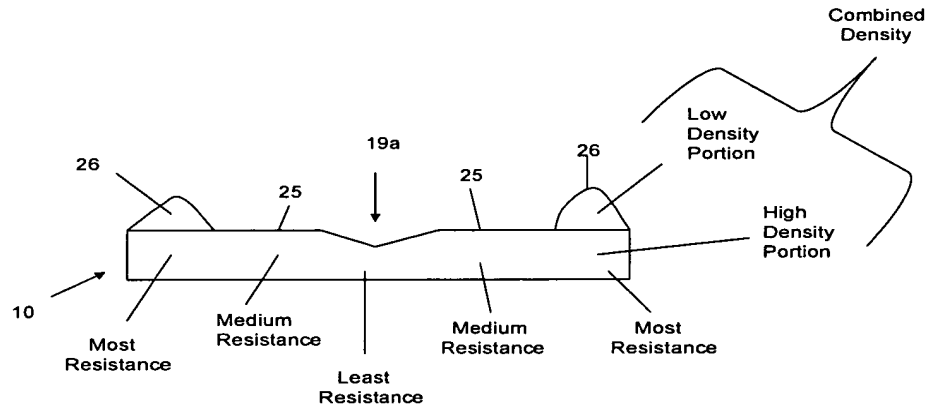
[1] References to "area 25" are being used for convenience and to refer to the side areas adjacent each side of groove 19/19a.

mind that an individual's kidneys are located at a level about equal to the mid-lumbar region, and above the iliac crests of the pelvis and above the sacrum. (See, page 4 of 5 of Exhibit B [Univ. Calf.: A Practical Guide to Clinical Medicine]; and Exhibit C [SEER Summary Staging Manual, page 233]). Thus, the foam pieces 26, which are identified by Perkins as providing kidney support, must be positioned high enough to actually hit the kidneys thereby locating the foam pieces 26 far above the sacrum level. If one were to argue that only the upper portion of the kidney pieces would be at the kidney level and that the bottom of the kidney pieces 26 were at the level of the pelvis bones, the pieces 26 would prevent the pelvis from moving rearwardly, again a concept and result that is directly opposite to the claimed invention here.

Perkins does say that the kidney supports 26 can have a lesser density than the rest of the foam 15/25 used. In fact, he states that he can use one of three different foam densities for the foam layer 15 (Nos. 3030, 2034 and 1445, respectively for small, medium and large sizes) and one density for the kidney pieces 26 (No. 1334). (See. Col. 2, lines 20-29). This supports the view set forth in the figures, noted above, that in the kidney area there are two different foams being used, for example the 1334 density form for the kidney pieces 26 plus the 3030 density foam for the layer 15/25, making that outer or end area the most dense and, in sum, the area that is providing the most resistance. That, too, is contrary to the claimed invention.

The sketch below shows a cross section through Perkins' back support at the end locations for the kidney pieces 26, the medium resistance foam layer at 25 and the centrally located groove 19a. Regardless of the foam density used for the main support, the area of the least resistance will be where the groove 19a is located. That is because the foam has been cut away or reduced in thickness at the center of the back rest and is point where the back rest is the thinnest. Since there is the least amount of foam in the groove 19a area that area can only provide minimal support. The two adjacent foam areas, 25, will have the next most resistance and will keep the groove area from having a great effect on the user as they will hold the groove area away from the users back. The outer or end areas, where two foam layers are used, layer 25 and the kidney pieces 26, will provide the most support due to the combined layers. From a

compression view point, the least compression or resistance will be at the thinnest point, in the center, the next adjacent areas 25 will exhibit a higher amount of compression or medium resistance, as they are thicker, and the most compression or the highest resistance will be present at the ends in the kidney areas where the resistance will be the combined result of the base foam 15/25 and the areas 26.



From this one can see that Perkins is teaching the exact opposite to the invention claimed here in terms of where resistance should be. In deed, Perkins is actually teaching away from the presently claimed invention, if it contains any relevant teachings, which is not admitted or conceded.

As claimed in this application, the most compression, or resistance is to be located in the central portion. Perkins shows the least resistance in his central portion. Perkins next forms the areas 25 adjacent groove 19a with a greater compression or resistance value than in the central groove 19a area. This is also opposite to the claimed invention where the claimed adjacent side

areas exhibit the least compression or resistance and less than the compression or resistance in the central portion. In Perkins, his areas 25 adjacent groove 19a exhibits greater resistance than the central because the foam is thicker and of the same density. Again, this is opposite of what is being claimed here. Further, Perkins teaches away from the concept, found in some of the present claims, of having a third area of compression located at the ends of the sacral support with a compression value in between those of the central portion its adjacent side areas. Perkins uses the combined compression of two foam layers, layers 15/25 and layer 26, making it have the combined effect of each layer and thus the greatest amount of compression, and larger than the compression in either in groove 19a or the two areas 25.

In addition, there is no teaching in Perkins of having the pelvis, or body structures adjacent each side of the sacrum, to nest rearwardly as the stiffer central portion supports and keeps the sacrum in a more forward location due to the higher compression or resistance of that portion of the support. In fact, the presence of pieces 26 in Perkins would resist such movement.

As noted previously, claims 1, 28, 32 and 34 have been amended to resolve an issue raised by the Examiner that relates to the fact the Perkins shows the application of "a force" on the lumbo-sacral area (L5-S1). What Perkins shows is a small force at the centrally located groove 19a, a greater amount adjacent the groove in areas 25 and the most where the stacking of layers 25 and 26 exist for kidney support. Since the present device has the objective of concentrating the greatest or highest amount of force, compression or resistance on the sacrum itself, by having a central portion apply the greatest level of compressive force and to direct that directly against the sacrum, the above claims each now claim that the central portion has a first compression value that is greater than the second compression value in the area adjacent the central portion. These two compression values, and the fact that the present invention deals with sacral support, distinguishes claims 1, 28, 32 and 34 from Perkins.

The above quoted portion from Perkin's specification explains that areas 25 are spaced apart to provide a continuation 19a of the groove 19. Groove 19-19a is in the center of his back rest. The continuation groove 19a is a recessed area that will not apply a force greater than areas

25. This is the reverse of this invention. Fig. 2 is a front view of the Perkins back support without the outer covering and shows that the grooves 19 and 19a exist in the front of the back rest which faces the seated occupant and against which the seated occupant will have contact. Thus, even if it was possible for a user to be affected by the bottom edge of the back rest (which is not believed to be the case), the sacrum, located at the center and bottom of the spine below the lumbo-sacral joint, would be located either in front of and/or below the groove continuation 19a on Perkins' back rest. The groove 19a not only curves away from the sacrum of a seat back user, but groove 19a would tend to hold foam away from and therefor shield the sacrum of the user thereby reducing any force that might be possibly applied, if it were even within the limits of Perkins' device, which is neither conceded nor believed to be the case. The groove 19a would provide little or no force against the sacrum, since as Perkins states "the purpose of [groove or slot 19] is to receive and accommodate bony prominences of the spine." Further, the relatively harder foam within areas 25, on each sided of grove 19a, will hold the muscles adjacent the spine and prevent the groove 19a from putting force on the sacrum. This is again directly opposite to the concepts claimed herein and prevents the nesting of the body structures adjacent the sacrum that is desirable.

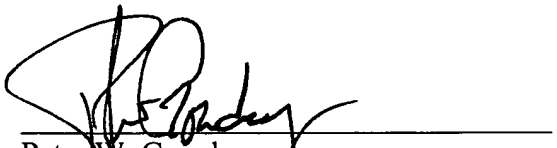
It should also be noted that items 15 and the recesses 12 are located adjacent the upper back or thoracic region and are thereby far above both the lumbar and the sacral area.

It is respectfully submitted that Perkins does not anticipate claims 1-4, 6, 7, 15-16, 19-21, 23-26, 28, 32, 34 or 37, and notice to that effect is respectfully requested.

Consequently, in view of the present amendment and in light of the above discussions, the outstanding grounds for rejection are believed to have been overcome and in condition for allowance. An early and favorable action to that effect is respectfully requested.

Respectfully submitted,

DAVIDSON, BERQUIST,
JACKSON & GOWDEY, L.L.P.



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Clinical Biomechanics of the Spine

Second Edition

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portion. These patterns have been documented in detail elsewhere.[F,124]

Actually, a study by Panjabi and colleagues has shown that all of the six degrees of freedom demonstrate coupling patterns of varying degree.[79]

There has been relatively more interest in the coupling of axial rotation and lateral bending. This is largely due to its relevance in the etiology, evaluation, and treatment of scoliosis. This coupling is also important in the mechanisms of injury in the cervical spine. Abnormal coupling patterns have been viewed and analyzed in the context of possible evidence of instability. Changes in coupling patterns have also been noted adjacent to spinal fusions. Finally, this particular coupling characteristic may have relevance in the basic biomechanics of different regions of the spine. Because of these important factors, which are discussed in various parts of this text, we've elected to prepare composites, which are shown in Figure 2-19.

Instantaneous Axis of Rotation

The shortcomings of current descriptions of the location of the instantaneous axis of rotation have been discussed.[D] The approximate locations of these centers for the thoracic spine are represented diagrammatically in Figure 2-20.

In a recent study using fresh cadaveric functional spinal units covering all levels of the thoracic spine,

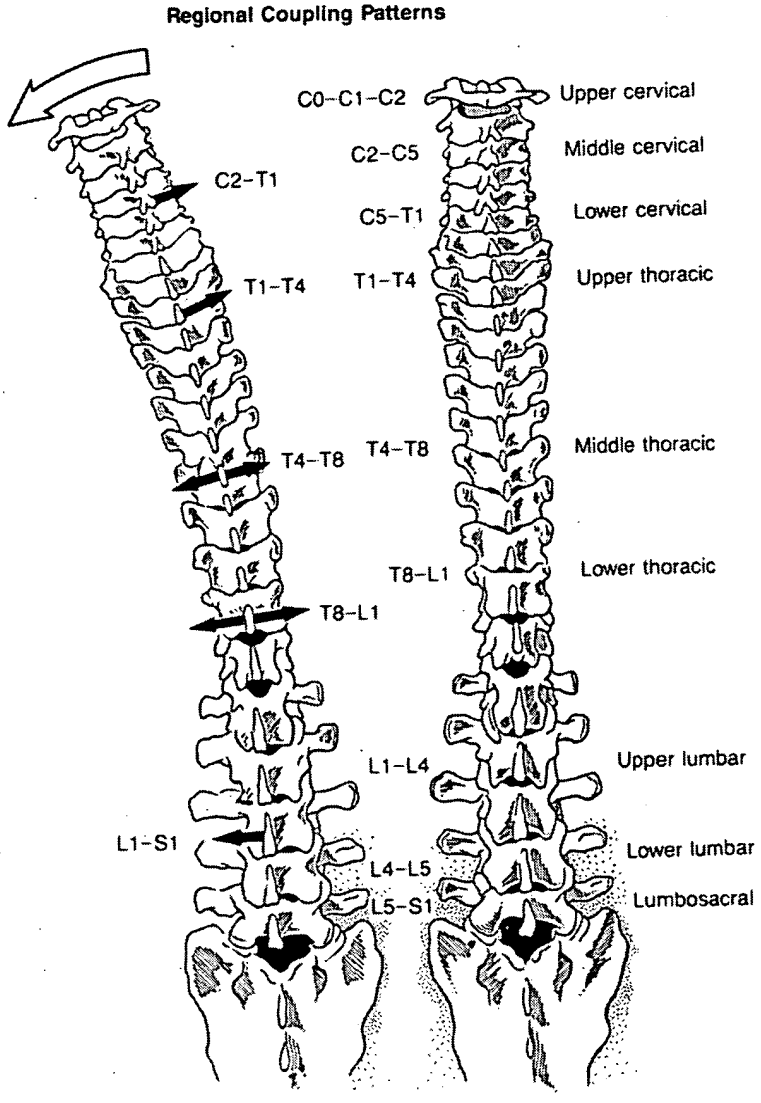

FIGURE 2-19 This diagram summarizes the coupling of lateral bending and axial rotation and depicts the new biomechanical subdivisions of the spine. The actual coupling is between ± z-axis rotation and ± y-axis rotation. It can also be thought of in terms of the direction of movement of spinous processes with left lateral bending. Note that in the *middle* and *lower* cervical spine as well as in the *upper thoracic* spine there are the same coupling patterns. In the *middle* and the *lower thoracic* spine, the axial rotation, which is coupled with lateral bending, can be in either direction, that is, it can be ± y-axis rotation. The direction of this axial rotation apparently varies between different specimens. In the *lumbar* spine there is − y-axis rotation associated with − z-axis rotation. That is, the spinous processes go to the left with left lateral bending. The same pattern is also present at the lumbosacral FSU.

UNIVERSITY OF CALIFORNIA, SAN DIEGO

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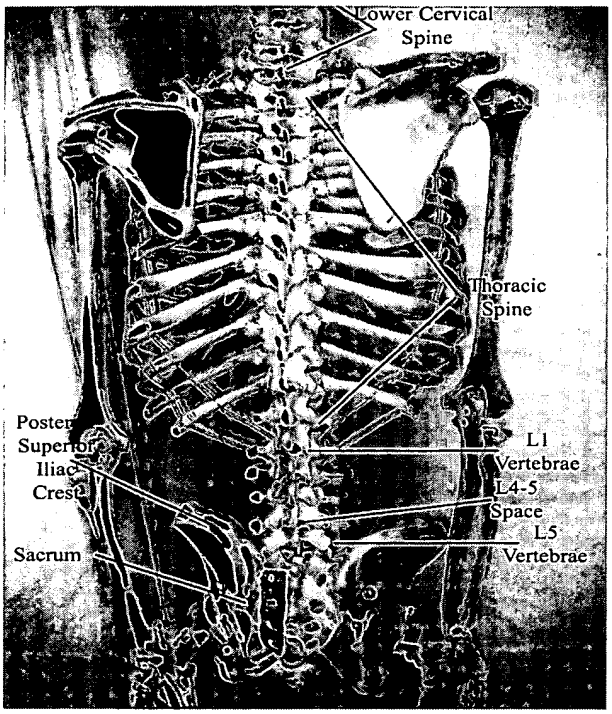
Musculo-Skeletal Examination

Low Back Pain

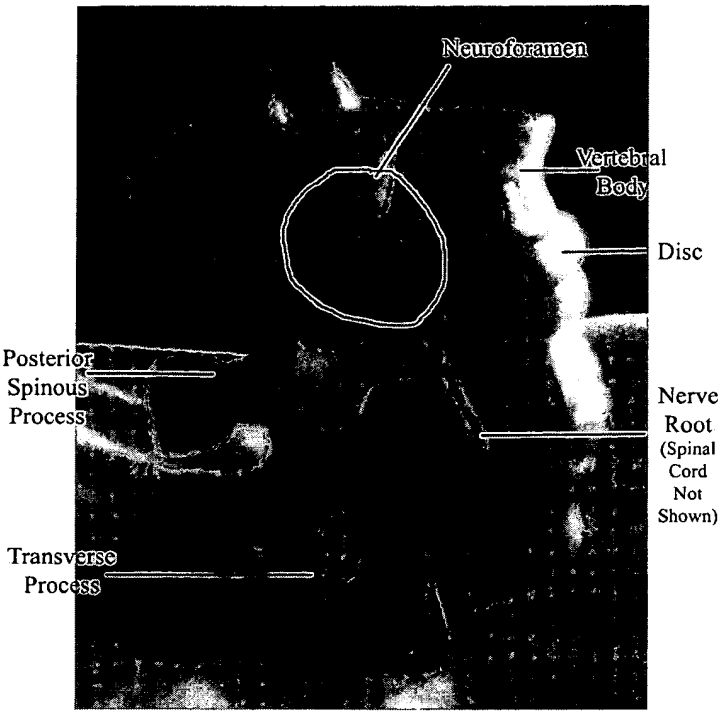
Low back pain is a very common condition. Examination and history provide important clues as to its etiology.

Function and Anatomy:

The lumbar spine must support a tremendous amount of weight, protect the spinal cord and yet still maintain flexibility that maintains range of motion. The low back is formed by 5 lumbar vertebrae and the sacrum. Each vertebrae articulates with the one above and below it in a precise fashion that helps to maximize function. The bones are covered by periosteum, which is innervated and thus generates pain if inflamed (see below). The vertebrae are separated by discs, which allow for smooth, cushioned articulation. The outer aspect of the disc is made of a tough fibrous tissue called the annulus fibrosis, while the inner aspect is gelatinous and known as the nucleus propulsus. Powerful ligaments connect the verterbrae to each other along their anterior and posterior aspects. The spinal cord runs in a bony canal, just posterior to the main body of the vertebrae. This space is well designed to protect the delicate nervous tissue of the cord. The vertebral column has regularly spaced lateral openings known as neuroforamina, through which nerve roots exit and travel to the target organs which they innervate. The actual cord ends at about the L1 level. Below this point, nerve roots (known as the cauda equine) drape down and fill the lower aspect of the spinal canal. The neuro formaina are identified by the vertebrae that are above and below it (e.g L5-S1 neuro foramen sits between the L5 and S1 vertebrae). Spinous processes make up the most posterior aspect of the spinal column and are palpable on exam. The rest of the structures (e.g. discs, spinal cord, nerve roots) are not palpable. In terms of surface landmarks, it's helpful to identify the posterior superior iliac crest. This point is roughly on line with the L4-5 intervertebral space.
Review of Spinal Anatomy.



Overview of Spine



Representative Segment of Spinal Column (Lateral View)

Common Benign Pain Syndromes--Symptoms and Etiology:

1. Non-specific musculoskeletal pain: This is the most common cause of back pain. Patients present with lumbar area pain that does not radiate, is worse with activity, and improves with rest. There may or may not be a clear history of antecedent over use or increased activity. The pain is presumably caused by irritation of the paraspinal muscles, ligaments or vertebral body articulations. However, a precise etiology is difficulty to identify.
2. Radicular Symptoms: Often referred to as "sciatica," this is a pain syndrome caused by irritation of one of the nerve roots as it exits the spinal column. The root can become inflamed as a result of a compromised neuroforamina (e.g. bony osteophyte that limits size of the opening) or a herniated disc (the fibrosis tears, allowing the propulsus to squeeze out and push on the adjacent root). Sometimes, it's not precisely clear what has lead to the irritation. In any case, patient's report a burning/electric shock type pain that starts in the low back, traveling down the buttocks and along the back of the leg, radiating below the knee. The most commonly affected nerve roots are L5 and S1.
3. Spinal Stenosis: Pain starts in the low back and radiates down the buttocks bilaterally, continuing along the backs of both legs. Symptoms are usually worse with walking and improve when the patient bends forward. Patient's may describe that they relieve symptoms by leaning forward on their shopping carts when walking in a super market. This is caused by spinal stenosis, a narrowing of the central canal that holds the spinal cord. The limited amount of space puts pressure on the nerve roots when the patient walks, causing the symptoms (referred to as neurogenic claudication). Spinal stenosis can be congenital or develop over years as a result of djd of the spine. As opposed to true claudication (pain in calfs/lower legs due to arterial insufficiency), pain resolves very quickly when person stops walking and assumes upright position. Also, peripheral pulses should be normal.
4. Mixed symptoms: In some patients, more then one process may co-exist, causing elements of more then one symptom syndrome to co-exist.

Red Flags:

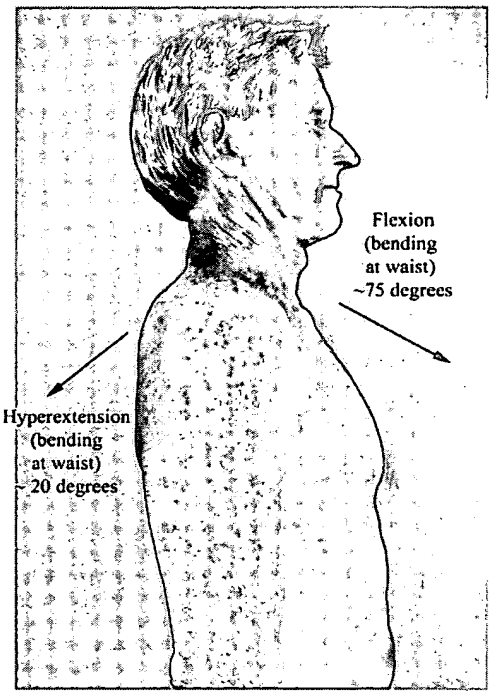
There are a variety of ominous processes that cause low back pain, particularly in older patients (> 50). These problems carry significant morbidity and mortality and mandate a focused and rapid evaluation (including lab and imaging studies) different from what is required for the relatively benign processes described above. Careful history taking and examination can help distinguish these problems. Historical keys include:

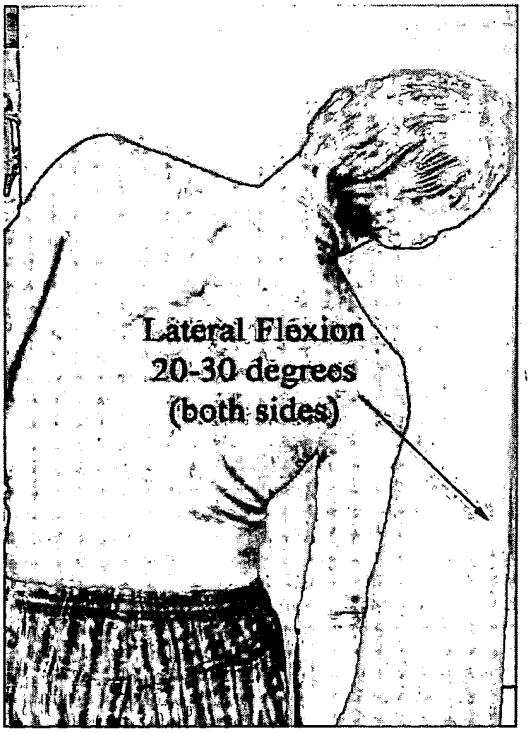
1. Pain that doesn't get better when lying down/resting.
2. Pain associated by systemic symptoms of inflammation (e.g. fever, chills), in particular in those at risk for systemic infection that could seed the spinal area (e.g. IV drug users, patients with bacteremia).
3. Known history of cancer, in particular malignancies that metastasize to bone (e.g. prostate, breast, lung).

4. Trauma, particularly if of substantial force.
5. Osteoporosis, which increases risk of compression fracture (vertebrae collapsing under the weight they must bear). More common as people age, women > men.
6. Anything suggesting neurological compromise. In particular, weakness in legs suggesting motor dysfunction. Also, bowel or bladder incontinence, implying diffuse sacral root dysfunction. Note: it can sometimes be difficult to distinguish true weakness from motor limitation caused by pain.
7. Pain referred to the back from other areas of the body (e.g. intra-abdominal or retroperitoneal processes). Could include: Pyelonephritis, leaking/rupturing abdominal aortic aneurysm, posterior duodenal ulcer, pancreatitis, etc.

Examination Keys:

1. Vital signs. In particular, pain may be reflected by increase pulse, BP or pain score (if asked). Also, temperature if concern re an infectious process.
2. Observe gait. Is it slow, limited by pain?
3. Look at the lumbar spine area. Any skin abnormalities suggesting underlying inflammation? Normal curvature is as follows: Cervical spine sweeps anteriorly, thoracic spine sweeps posteriorly, and lumbro-sacral spine sweeps anteriorly.
4. Range of motion testing should include forward flexion, hyperextension, lateral flexion, and rotation.

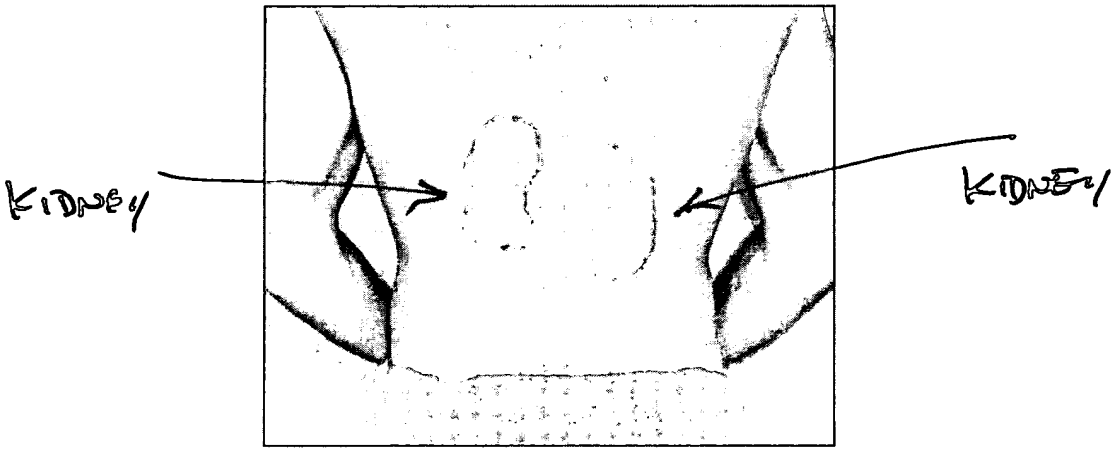




5. Can the patient point to the precise area of the pain? Is it along the vertebral column? Para-spinal, as might occur with spasm? Radiating down the legs as would occur with nerve root irritation?
6. Palpate the spine. Processes that inflame the bone (e.g. compression fracture, osteomyelitis, metastatic disease) will generate pain when the affected vertebrae is palpated or percussed.

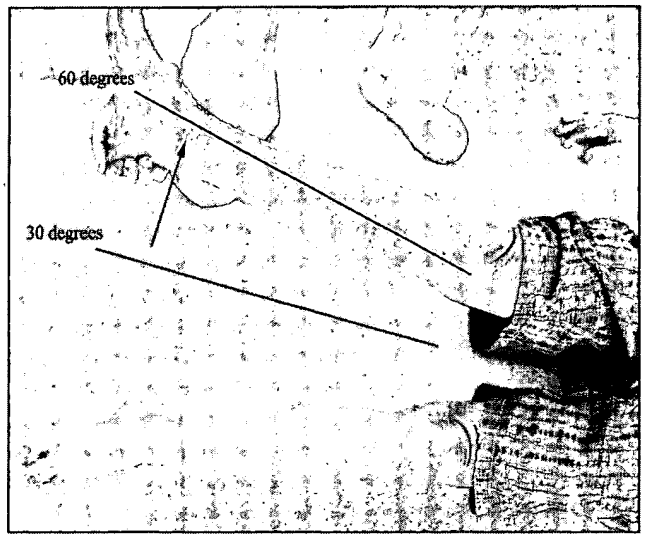
Spine Percussion

7. Is the pain in the costo-vertebral angle area, suggestive of a kidney infection?



Location of kidneys drawn on back. In the setting of kidney infection (pyelonephritis), percussion over this area will cause pain.

8. If the patient's complains of a radiating type pain down one leg, suggestive of nerve root irritation, proceed as follows:
   a. Ask the patient to lie down on their back.
   b. Have the patient completely relax the affected leg.
   c. Cup the heel of their foot and gently raise the leg. If there is nerve root irritation, the patient will experience their typical pain when the leg is elevated between 30 and 60 degrees. This is referred to at the "straight leg raise test" and is sensitive for identifying root pathology (i.e. if it does not reproduce pain, root irritation unlikely). Sensitive (75-90%), but not specific. Therefore, negative test helps rule out nerve root irritation as cause of pain.
   d. If the straight leg test is positive, repeat the same test on the opposite leg. This is called the crossed straight leg raised test and is 85-95% specific for root irritation, but not sensitive. Therefore, positive test makes root irritation the likely etiology of the symptoms.



Leg Raise Test

9. Assess bilateral lower extremity strength. In particular, if concern that nerve root pathology has lead to motor dysfunction (quite uncommon) check the following: a. Resisted great toe extension (extensor hallicis longus), mediated by the L5 nerve root. b. Walking on toes, as plantar flexion is mediated by the S1 root.
10. Reflexes, in particular the Achilles, which is a function of the S1 root.
    Detailed review of neurologic examination.
11. Distal sensation, paying attention to the L5 and S1 dermatomes.
    Dermatome Map University of Scranton.
12. If patient's note any bowel or bladder symptoms, assess sacral nerve root function as follows:
    a. Rectal tone: Patient should be able to contract anal sphincter around examining finger when directed to do so.
    b. Saddle area anesthesia: This is the region around the rectum, genitalia and inner thighs. Patients should be able to easily distinguish light touch and pin prick.
    c. Post Void Residual: Patient's should normally be able to completely empty their bladders. In acute sacral root dysfunction, this may be compromised. This can be assessed by using either a bedside bladder scan or placement of a foley catheter. While not part of the typical exam, it is important is this setting.
13. Gently internally and externally rotate the hip. In pyriformis syndrome internal rotation will stretch an already tight external rotator, causing further compression of the underlying nerve. This should reproduce the patient's symptoms. Straight and crossed leg raising will not reproduce symptoms.
    University of Washington Case Study, pyriformis syndrome. Click on "Lower Case 1: posterior thigh pain."
14. Check pulses in feet to assure that symptoms not related to peripheral vascular disease.
    Detailed review of lower extremity examination.
15. If any concern that symptoms are referred from the abdomen, a detailed exam of this area is performed. Also, if concern that back pain is a manifestation of systemic illness, appropriate detailed general exam should be performed.

Knee Exam	Shoulder Exam	Hand Exam	Elbow	Hip Exam	Lower Back Exam

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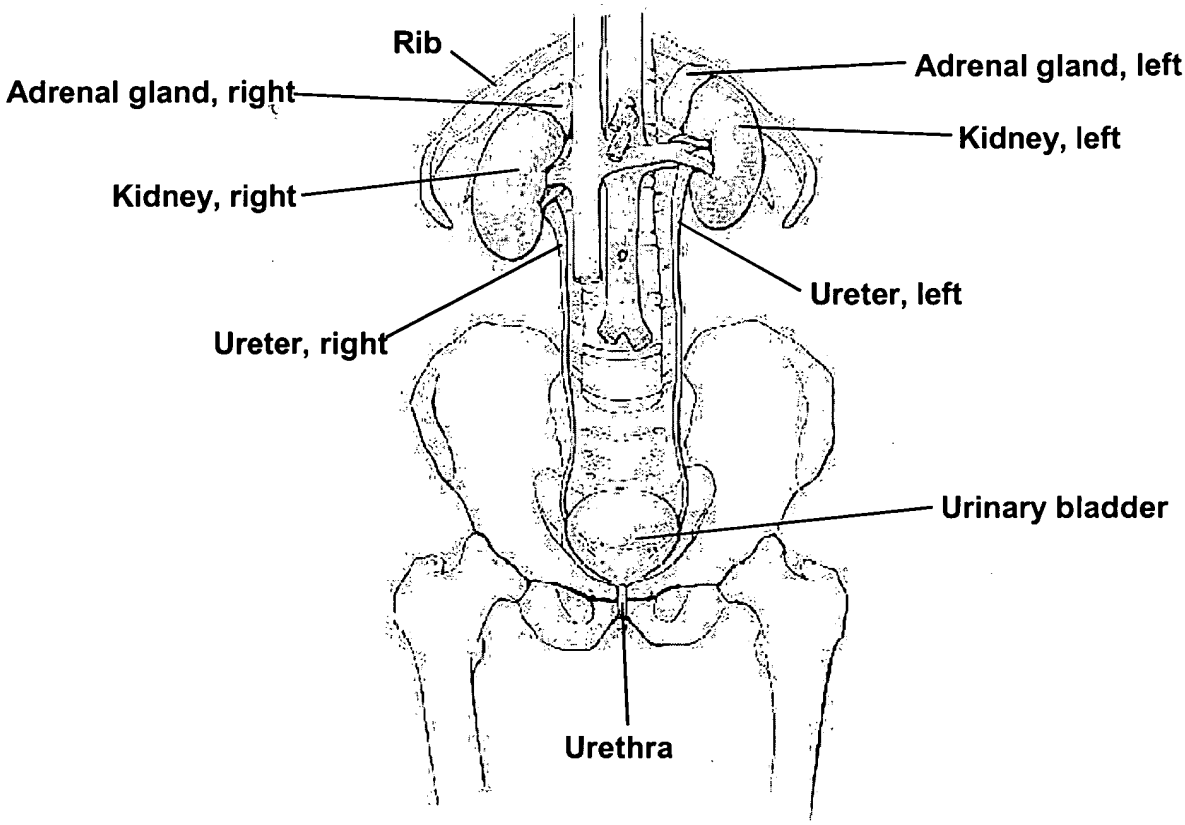
ANATOMIC DRAWING OF THE URINARY SYSTEM



THE URINARY SYSTEM